HIV Prevention Trials Network

Clarification Memorandum # 03 to:

HPTN 059, Phase II Expanded Safety and Acceptability Study of the Vaginal Microbicide 1% Tenofovir Gel, Version# 2.0, Dated 13 March 2006

IND #55, 690

Date of Clarification Memorandum: 16 May 2007

Section 1: Deletion from the HPTN059 Protocol Team Roster

Protocol Team Roster (Page vi) to be updated to delete:

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Section 2: Summary of Clarifications and Rationale

The procedures clarified in this memorandum have been approved by the NIAID Medical Officer and are to be implemented immediately upon issuance. IRB approval of this Clarification Memorandum is not required by the sponsor; however, investigators may submit the clarification memo to the IRBs/ECs overseeing the study at their site for their information.

This clarification memo is official HPTN 059 protocol documentation. It is effective immediately. A copy of this memo must be retained in each study site's Essential Documents file for HPTN 059.

No change in the informed consent form are necessitated by or included in this Clarification Memo.

The primary goal for this clarification memo is:

To develop the following operational guidance to eliminate inconsistency and reduce any ambiguity in the interpretation and application of instructions for PK level collection across study sites.

Section 3: Implementation

Text to be deleted is noted below by ~~strikethrough~~; text to be added is noted below in **bold.**

1. Section 1.3.5 (Page 8 of 65), first paragraph, third sentence will be changed to:

   In order to obtain an assay**,** ~~for one~~ **blood will be collected approximately** two to six hours **post-dose** from each participant, participants in the daily dosing arm will be asked to insert their daily study gel dose the morning of the visit…

2. Section 2.4.1 (Page 13 of 65), fourth paragraph, will be changed to:

   Additionally at the Week 20 Visit participants in the daily use arm will be asked to insert their daily dose of study gel ~~at least~~ **approximately** two to six hours prior to their visit, and participants in the coitally dependant arm will be asked to insert one dose of study gel ~~at least~~ **approximately** two to six hours prior to the visit. A blood draw will be taken for PK testing **approximately** two to six hours post-dosing.